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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

LEWIS, KIM M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,949

Applicant(s)

CARLSON ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-23 and 25 is/are pending in the application.
- 4a) Of the above claim(s) 25 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 is/are allowed.
- 6) ☒ Claim(s) 13-19, 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 11/22/05 has been received and made of record. As requested, claims 13 and 17 have been amended, and claim 25 has been added.
2. Claims 13-23 and 25 are pending in the instant application.

Election/Restrictions

3. Newly submitted claim 25 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly submitted is directed to a product, while previously presented claims 1-24 are directed to a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with a materially different product such as a corn or bunion pad.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 25 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5, 397, 628 ("Crawley et al.").

As regards claim 13, Crawley et al. disclose applicant's claimed invention. More specifically, Crawley et al. disclose and a method for a support (a laminated, air permeable cellular rubber, body protection material with porous, expanded polytetrafluoroethylene (PTFE) layer) supporting a portion of a human body having support bones, tissue around the support bones and skin on an outer side of the tissue, including selecting pressure regions of high loads when the load is carried between the object and the human body supported, applying one or more selected individual patches interfaced between the object and the skin in the selected regions, each selected individual patch having defined peripheral edges to encircle an entire individual patch, the selected patches being made of material having an exposed surface of low friction within the peripheral edges (col. 2, lines 38-45), and adhesively securing a patch in each selected area to one of the object and the tissue (Example 3). The applicant should note that the patch is unattached to the knee brace in Example 3, unit adhesively secured thereto.

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As regards applicant's recitation of a friction management method, the examiner wishes the applicant to note that where the preambular language is part of the definition of the invention, it provides a limitation. *Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 7 USPQ2d 1315 (Fed. Cir. 1988). Where, however, the preambular language states a purpose or intended use of the invention, it is not a limitation, but merely an indication of a possible use or the environment in which the invention operates. *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 228 USPQ 90 (Fed. Cir. 1985). In this instance, the preambular language is not considered a limitation.

Furthermore, both the summary of the invention and the examples of Crawley et al., make it clear that the protective material is to be used to decrease the amount of friction between the user's body and an object (e.g., a knee brace as disclosed in Example 3).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawley et al.

As regards claim 14 and 15, Crawley et al. fail to teach a shoe being the object and the region being the metatarsal-phalangeal joint region, and the region support begin the calcaneous. However, at col. 1, lines 23-28, Crawley et al. disclose "...and other body portions requiring some support while still allowing some flexibility or movement". Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Crawley et al to include supporting regions other than those explicitly disclosed by Crawley et al. as needed.

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10. Claims 13, 16, 17, 18, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,732,578 ("Pollack") in view of Crawley et al.

As regards claims 13 and 16, Pollack discloses a management method for a prosthetic device having a socket for receiving a portion of a limb to be supported and an exposed surface loading against the limb having support bones, tissue around the support bones and skin on an outer side of the tissue. The method includes selecting pressure regions of high loads when the load is carried between the exposed surface of prosthetic device and limb, and applying a pad between the device and the skin in the selected regions (col. 1, line 43-col. 2, line12).

Pollack fails to teach a plurality of pads, that the pads have an exposed surface of low friction, and that the pads are adhesively attached to the object or tissue. However, at col. 3, lines 32-34, Crawley et al. teach the use of a low friction material as a stump covering for amputees in order to minimize friction between the skin and the article. This will help to minimize irritation of the skin. At col. 6, lines 14-35, Crawley et al. further teach the use of adhesive to apply the low friction material to a knee brace, thereby providing a teaching for adhesively attaching low friction material (pads/patches) to an object.

In view of Crawley et al., it would have been obvious to one having ordinary skill in the art to both modify Pollack by treating the pad with a low friction material in order to minimize friction between the skin and the article and to adhesively adhere the pad with a low friction material to an object in order to maintain the pad in place during use.

The applicant should note that the pad is unattached to the object until adhesively attached by the modification in view of Crawley et al.

As regards the use of one pad instead of a plurality of pads, Pollack teaches the high pressure points can be alleviated by one pad. It has been held that duplicating the components of a prior art device is a design consideration within the skill of the art. *In re Harza*, 274 f.2d 660, 124 USPQ 378 (CCPA 1960).

As regards claim 17, Pollack inherently discloses a method of reducing trauma to tissue supported on an object including the steps of selecting a plurality of support regions of high load where shear load on tissue is likely to cause damage (this is accomplished by placing the device on the user to determine the high load areas, and providing a separable, individual patch having a peripheral edge defining the patch between each of the plurality of the regions of high load and an object supporting the tissue.

Pollack fails to teach low friction patches and adhesively securing each patch to one of the tissue and the object. However, at col. 3, lines 32-34, Crawley et al. teach the use of a low friction material as a stump covering for amputees in order to minimize friction between the skin and the article. This will help to minimize irritation of the skin. At col. 6, lines 14-35, Crawley et al. further teach the use of adhesive to apply the low friction material to a knee brace, thereby providing a teaching for adhesively attaching low friction material (pads/patches) to an object.

In view of Crawley et al., it would have been obvious to one having ordinary skill in the art to both modify Pollack by treating the pad with a low friction material in order

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to minimize friction between the skin and the article and to adhesively adhere the pad with a low friction material to an object in order to maintain the pad in place during use.

The applicant should note that the patch is independent of the object adjacent the tissue.

As regards the use of one pad instead of a plurality of pads, Pollack teaches the high pressure points can be alleviated by one pad. It has been held that duplicating the components of a prior art device is a design consideration within the skill of the art. *In re Harza*, 274 F.2d 660, 124 USPQ 378 (CCPA 1960).

As regards claim 18, Crawley et al. disclose PTFE.

As regards claim 19, it is noted that the step which recites, "wherein the selecting step includes identifying support regions where low friction surface patches are omitted" is a mental step which is obviated by the method disclosed in Example 3. This mental step is not a factor in determining patentability because whether or not one determined support regions where low friction surfaces patches are omitted, is not part of the physical steps required to reduce trauma to tissue supported on an object. Therefore, even though the intended use of the prior art method in Example 3 was to place the material into a knee brace to inherently reduce trauma, the method of claim 3 obviates the claimed invention because the same action was carried out, regardless of the intent of the action.

As regards claim 21, Pollack discloses at col. 3, lines 8-12, the step of adding an additional pad after the tissue has been loaded against the object for a period of time.

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Once modified to include the low friction pads, one having ordinary skill in the art would have been further motivated to add an additional low friction pad.

As regards claim 22, Crawley et al. does not disclose that the adhesive is permanent; therefore the patch is inherently removable.

Allowable Subject Matter

11. Claim 23 is allowed.
12. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's primary arguments are that the Crawley et al. patent does not suggest or disclose trauma prevention due to friction, and that Crawley et al. does not teach an individual patch that is "independent of the support object or any other object adjacent the tissue" until it is adhesively secured. The examiner disagrees with both arguments.

First, Crawley et al. discloses at col. 1, lines 43-46, that PTFE adds a high degree of lubricity to the inner surface of the body protection material. This lubricity allows for a small amount of relative movement between the material and the skin. Clearly, the addition of the PTFE decreases friction between the skin and the material. Thus, reducing the trauma associated with the skin and material.

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As to applicant's argument relating to an individual patch that is "independent of the support object or any other object adjacent the tissue" until it is adhesively secured, the examiner contends that the claim 13 does not state what applicant is arguing. Additionally, example 3 of Crawley et al. disclose a patch that is independent of a new brace until it is adhesively secured thereto (col. 6, lines 14-46).

In response to applicant's argument regarding Pollack and Crawley et al., specifically, that both Pollack and Crawley et al. fail to teach the invention as presently claimed, note the rejection and arguments above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

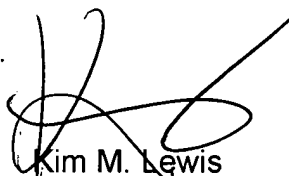
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
February 22, 2005